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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/828,874	04/10/2001	Jocl S. Douglas	018176-381	1056

7590 07/18/2003

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EXAMINER

SMITH, ZANDRA V

ART UNIT

PAPER NUMBER

2877

DATE MAILED: 07/18/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	09/828,874	DOUGLAS ET AL.
	Examiner Zandra V. Smith	Art Unit 2877

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 04 March 2003.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 8-19 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) 10,11,16 and 17 is/are allowed.
- 6) Claim(s) 8,9,12-15,18 and 19 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ . | 6) <input type="checkbox"/> Other: _____ . |

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DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 8-9, 12-15, and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over *Grant et al. (EP 573598)* in view of *Douglas et al. (WO 98/19159)*, cited by applicant.

As to claims 8-9, Grant discloses a test strip holding and reading meter, comprising:
an electronic printed circuit board having alignment fixturing;
an optics system for alignment with the removable test strip, the optics system comprising an emitter, prisms, lenses (col. 10, lines 25-30), and a detector and mounted on the printed circuit board (col. 9, lines 32-50);
a housing (col. 7, lines 10-15);
an optics block holder mounted in the printed circuit board for aligning the test strip and positioning the optics system to focus light (col. 9, lines 32-50); and
a processor (col. 18, lines 45-58). Grant differs in that the processor does not control the assay system in accordance with calibration information, however to do so is well known as taught by Douglas. Douglas discloses an analyte testing system that includes a removable calibration chip and a processor to control the assay system in accordance with calibration information (page 16, lines 5-14). It would have been obvious to one having ordinary skill in the art at the time of invention to include a removable calibration chip and a processor to control the

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assay system in accordance with calibration information to compensate for lot differences in the reagent in each strip.

As to **claims 12-13, and 19**, Grant discloses a test strip holding and reading meter, comprising:

an electronic printed circuit board having alignment fixturing;

an optics system for alignment with the removable test strip, the optics system comprising an emitter, prisms, lenses (col. 10, lines 25-30), and a detector and mounted on the printed circuit board (col. 9, lines 32-50);

a housing (col. 7, lines 10-15); and

an optics block holder mounted in the printed circuit board for aligning the test strip and positioning the optics system to focus light (col. 9, lines 32-50).

Grant fails to specifically provide the processor controlling the assay system such that the test strips are assays up to a predetermined expiration date, however to do so is well known as taught by Douglas. In the same field of endeavor Douglas discloses an analyte testing system that includes a microprocessor controlling the system such that the test strips are assays up to a predetermined expiration date of one, two, or more test strips (page 18, lines 9-17). It would have been obvious to one having ordinary skill in the art at the time of invention to include a processor controlling the assay system such that the test strips are assays up to a predetermined expiration date to avoid false readings.

As to **claims 14-15**, Grant and Douglas discloses everything claimed, as applied above, in addition, Douglas discloses a set of one or more test strips containing at least two test strips (pg. 16, line 10 and pg. 17, lines 10-18). It would have been obvious to one having ordinary skill in

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the art at the time of invention to provide a set of one or more test strips containing at least two test strips since calibration is based on the lot of test strips, providing at least two strips will eliminate the need to calibrate the system for each strip.

Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over *Grant et al. (EP 573598)* and *Douglas et al. (WO 98/19159)*, cited by applicant and further in view of *Poto et al. (5,795,543)*.

As to **claim 18**, the system of Grant and Douglas discloses everything claimed, as applied above, with the exception of the predetermined expiration date corresponding to the housing, however to do is well known as taught by Poto. In the same field of endeavor Poto disclose a disposable electronic diagnostic instrument that includes an expiration date corresponding to the housing (col. 2, lines 15-34). It would have been obvious to one having ordinary skill in the art at the time of invention to include an expiration date that corresponds to the housing to avoid the necessity of recalibration or cleaning of the instrument.

Response to Arguments

Applicant's arguments with respect to claims 8-19 have been considered but are moot in view of the new ground(s) of rejection.

Allowable Subject Matter

Claims 10-11 and 16-17 are allowable over the prior art of record.

The following is a statement of reasons for the indication of allowable subject matter: the prior art of record, taken alone or in combination, fails to disclose or render obvious a processor controlling the assay system such that a predetermined number of test strips are assayed based on signals from the light detector.

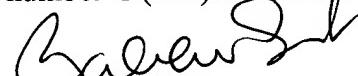
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Fax/Telephone Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zandra V. Smith whose telephone number is (703) 305-7776. The examiner can normally be reached on 8:00 a.m. - 4:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frank G. Font can be reached on (703)308-4881. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-7722 for regular communications and (703) 308-7722 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-0539.



Zandra V. Smith
Primary Examiner
Art Unit 2877

May 30, 2003